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DEBATE-COMMENTARY

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The unintended consequences of the 340B safety-net drug discount program

The 340B Drug Pricing Program was created under the Veterans Health Care Act of 1992 to increase access to outpatient medications for low-income and uninsured patients.[1] This program allows qualified hospitals and other health care providers, known as covered entities, to purchase certain outpatient medications at substantially discounted prices from manufacturers.[2] These covered entities are then able to receive the full reimbursement from both private and public insurers to dispense and administer these medications.[3] It is the hope of the Federal government that the 340B program enables covered entities to "stretch scare federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] However, it remains uncertain whether the 340B program actually results in improved access to low-income and uninsured patients.

In order to understand the 340B Drug Discount Program, it is helpful to look back at why the program was enacted in the first place. The 1990 Omnibus Budget Reconciliation Act (OBRA) created the Medicaid Drug Rebate Program that required pharmaceutical companies to offer state Medicaid programs their best prices in the market.[5,6] Prior to OBRA, pharmaceutical companies often made special discounts available to safety-net hospitals to support their charitable and uncompensated care. Once the Medicaid Drug Rebate Program was in place, safety-net providers found that pharmaceutical firms would no longer sell products at deeply discounted prices because the safety-net prices would inadvertently serve as the Medicaid best market price. Thus, the 340B program was narrowly crafted to provide specific relief to safety-net hospitals by restoring their pre-OBRA discounts while exempting the prices available to 340B hospitals and prices on the Federal Supply Schedule from becoming the basis of the market price used in the Medicaid best price calculation.

The 340B program provided safety-net hospitals that qualify as covered entities the opportunity to purchase outpatient medications at highly discounted prices. In fact, under the law, pharmaceutical companies are required to offer 340B hospital discounts in order to be eligible to participate in the Medicaid program.[7] While the exact discount prices are confidential, the Department of Health and Human Services reports that 340B providers are offered discounts of between 25 percent to 50 percent on outpatient drug prices.[8]Given the law's focus on safety-net providers, the 340B program did not preclude eligible providers from generating profits from the sale of the discounted products nor were there requirements in the law that profits obtained from the discounts would be directed to charity care purposes.

1 | DETERMINATION OF 340B ELIGIBILITY HAS EXPANDED OVER TIME

The 340B program originally included approximately 90 safety-net hospitals,[5,6] and the type and number of participating providers has grown over time. It now includes federally qualified health centers, disease-specific programs (public AIDS Drug purchasing programs, black-lung clinics, and hemophilia treatment centers), and hospitals with a disproportionate share (DSH) percentage of at least 11.75 percent.[9,10] The impact of the program for covered entities expanded starting in 1996, when the Health Resources and Services Administration (HRSA) (the federal agency that manages the 340B program) allowed 340B covered entities to dispense medications acquired under the discount program to patients through contract pharmacies.[11]

Given the significant benefits available under the program, participation in the program was very attractive. Covered entities grew from the original cohort of 90 entities to 591 in 2005 and 1,673 in 2011, including 1/3 of all US hospitals at the time.[1,6] The Affordable Care Act (ACA) also led to increases in the number of covered entities due to expansion of the program to include critical access hospitals, freestanding cancer hospitals, and rural treatment centers as well as through the expansion of Medicaid, which led to more hospitals becoming 340B-eligible using the DSH criteria.[3,10] Importantly, orphan drugs are excluded from the program for some indications for entities joining the program after 2010.[9]

By 2015, 40 percent of all US hospital were enrolled as 340B entities.[12] By 2017, there were more than 12,000 covered entities (340B participants including hospitals and other eligible clinical programs or sites) and 38,000 total sites (subentities of the participating hospitals or contract pharmacies) participating in the 340B program.[13] Covered entities will pay contract pharmacies fees for serving eligible 340B patients, but can retain a profit on the transaction as if the medications were dispensed by the covered entity.

2 | 340B PROGRAM FINANCIAL IMPACT

For the purposes of the 340B program, discounted drugs are available to the covered entity for the care of patients regardless of insurance status. HRSA has described "patients of the entity," eligible to receive the discounted drugs, as those where the covered entity maintains a medical record of the patients, confirms that patients

receive care from a provider associated with the covered entity, and confirms that patients receive a range of health services beyond prescriptions.[14,15]

The Government Accountability Office (GAO) reported that the 340B program accounted for $6 billion in outpatient drug spending, or roughly 2 percent of US pharmaceutical spending in 2011.[12] This spending increased to $12 billion in 2015.[16] Covered entities saved about $3.8 billion in 2013 on outpatient drugs, which grew to an estimated $6 billion in 2015.[3,10] One cross-sectional study analyzed outpatient claims for Medicare patients from 2013 to 2016 and found that hospitals received Medicare 340B revenue of $2.1 billion in 2013 increasing to $3.7 billion in 2016, with per-hospital profits related to the drug discounts of $2.5 million (Medicare pays all providers, 340B and non-340B, the same amount for Part B drugs irrespective of acquisition cost). The authors note that these numbers are the lower bound of total revenue from the 340B program as it does not consider drugs dispensed by hospital contract pharmacies nor revenue and profits from commercial insurer payments for discounted drugs.[17]

A budget impact analysis examining the treatment of patients with hepatitis C from 2015 to 2016 found that providers would generate a net profit of $930 per patient in a 340B eligible organization compared to a loss of $370 per patient in a noneligible setting.[18]

3 | IMPACT OF 340B ON CARE PATTERNS

The growth of the 340B program has been associated with significant changes in the practice of medicine. As the prices of medicines administered or delivered in the outpatient setting have increased, the profits from 340B participation have also increased. The result has been an increasing divergence between the economics of community-based medicine and hospital outpatient practice at a 340B covered entity. This spread has created a strong incentive for 340B participating hospitals to purchase community-based practices that have the greatest opportunity to benefit from dispensing medications acquired through the 340B program, including practices in oncology, ophthalmology, and rheumatology.[19] Concurrently, these same practices also benefit from provider leverage in establishing higher payment rates for privately insured patients in the hospital outpatient setting.[20] In one paper examining the highest-volume medical specialties in Medicare in 2012 and 2013, medical oncology had the highest proportion of hospital outpatient department (HOPD) billing in 2012 and 2013 (35.0 percent and 38.3 percent, respectively) and the greatest absolute change (3.3 percent) between the years.[21] Another study found that hospitals eligible for the 340B program had more hematologist-oncologists (230 percent more) compared to non-340B participating hospitals.[19]

The GAO reported that the costs of oncology services are significantly higher in 340B sites than comparable non-340B sites ($4779 vs $3632 in 2008; and $7801 vs $5432 in 2012).[12.] This discrepancy did not appear to be explained by health status differences but implies that the 340B sites on average either dispensed a higher quantity of prescription drugs or more expensive drugs. Over the same time period, 340B eligibility was associated with significantly more Part B drug claims billed per year in hematology-oncology (90 percent increase, $P = .001$), ophthalmology (177 percent increase, $P = .03$), and rheumatology (77 percent increase, not significant at $P = .12$).[19]

In other work, authors found the probability of cancer drug administration occurring in hospital outpatient departments (HOPDs) versus physician offices increased 7.8 percentage points more in new 340B markets. That same study found no increase in drug spending for Medicare patients receiving care at a 340B facility, but an increase in Medicare payments for other cancer care of $1162 in markets newly gaining a 340B hospital compared with markets with no 340B hospital (an 8.4 percent increase).[22]

Overall, MedPAC reported that in the period 2012 to 2017, the volume of outpatient prospective payment system (OPPS) clinic visits increased by 34 percent and the volume of chemotherapy administration visits rose 45 percent, while there was a concurrent decline in freestanding office offices of 0.6 percent and office-based chemotherapy administration visits of 15.2 percent. MedPAC concluded: "The shift of clinic visits and chemotherapy administration from physician offices to HOPDs is important because it increases Medicare program spending and beneficiary cost-sharing liability."[23]

Beyond oncology, one study analyzing Medicare Part D claims for novel (and expensive) hepatitis C treatments in 2016 found that 30 percent-40 percent of all claims came from 340B eligible organizations, compared to just 14 percent of claims for all Medicare Part D drugs.[24] In this case, the hepatitis C treatment was a supply of oral medications dispensed by 340B providers which could then profit from the discount on these high-priced medications.

4 | EXAMINING CHARITY CARE AT 340B HOSPITALS

One of the greatest concerns around the impact of the 340B is that the benefits may not be going to the intended low-income and uninsured patients. This question persists because the 340B program never explicitly tied covered entities to charity care service obligations as a condition of participation (nor even to charity care reporting requirements).

Recent studies report that participating 340B-participating hospitals based on DSH criteria appear to be no more engaged in providing care to vulnerable populations than nonparticipating, nonprofit, and public hospitals.[12,25] Another study found that DSHs that registered for 340B in 2004 or later generally served communities with fewer low-income people and with higher rates of health insurance compared to similar non-340B registered hospitals.[26] MedPAC reported that 40 percent of 340B hospitals provided less than the national median share of uncompensated care (3.6 percent) in 2014 as reported in Medicare cost reports.[3]

While 340B was originally intended to support safety-net hospitals in their charity mission, the expansion of the 340B program

leaves an open question of whether the program actually results in increases in charity care.

In this issue of HSR, Nikpay et al[27] provide a carefully constructed analysis to address this question at hospitals using a unique dataset constructed from Medicare hospital cost reports, American Hospital Association Survey data, and Schedule 990 nonprofit hospital tax returns. They examine hospital performance from 2011 to 2015, as noted a period of expansion in 340B participation. With this dataset, the authors were able to assess whether 340B participation impacted several measures of charity care: charity care, community benefit spending, charity care policies, and low-profit service line provision.

Overall, the results suggested that 340B participation had limited impact on charity care at covered entities. New 340B participation did not increase provision of uncompensated care or community benefit spending, nor the probability of offering low-profit medical care service lines. Participation was associated with an increase in charity care spending (a subset of the unchanged community benefit spending) and a modest increase in income eligibility for discounted care (an increase of 19 percent to 313 percent of FPL which is still less than the upper income limit of 400 percent FPL eligible for a subsidy to purchase health insurance in a marketplace as a part of the ACA). The authors conclude, "340B participation increases hospital charity care by a very small amount (<$1M) suggests that, even ignoring reductions in other community benefit spending, the associated increase in safety-net care is small relative to program revenues."

5 | POLICY IMPLICATIONS

Advocates for the 340B program will be disappointed in these results. This modest program, implemented to address an inadvertent consequence of the Medicaid Drug Rebate Program, has seen its impact expanded, reverberating throughout the health care system. The structural financial advantage resulting from 340B discounts has contributing to changes in the provision of care by moving services from freestanding clinics which lack access to 340B discounts to hospital outpatient sites which have access to the program.

Overall, the literature now suggests that the 340B program has offered a major financial windfall to covered entities with little of the benefit targeted toward safety-net providers who care for low-income patients. Further, 340B has placed hospitals in a position of benefiting financially from increases in drug prices (the higher the price, the greater the financial benefit from the 340B discount, even under Medicare).[18] To place this impact in perspective, 50 percent of the increase in the cost of care in the United States from 1996 to 2013 was due to price increases and increases in service intensity (in part a reflection of the migration to the hospital outpatient setting).[28] The evidence seems to suggest that the 340B program, coupled to health system pricing leverage in the commercial market, has played an important role in these findings.

CMS has been trying to address what it considers an overpayment to covered entities under the Medicare program. Covered entities are able to purchase medications at a substantial discount to the market price (defined under Part B as the average sales price [ASP]). Medicare Part B drugs are reimbursed by the outpatient prospective payment system (OPPS) at 106 percent of each drug's ASP, not currently adjusted for the lower drug acquisition cost for 340B providers, resulting in a substantial difference between Medicare payments rates and the acquisition cost of Part B drugs.[3] This allows 340B eligible providers to generate significant profits when administering Part B drugs.[29] In 2018 and 2019 rules (and again in the proposed 2020 rules), CMS reduced the payment for 340B hospitals by 25 percent.[30] However, to date this payment rule has not been implemented and is under review by the Federal courts.[31]

Other efforts to reform the Medicare Part B payment structure (moving from ASP + 6 percent to a different formula) have also faced challenges when not considering the impact of the 340B program. Any adjustment to the fee schedule will have a disproportionate impact on community practices which do not have the financial cushion of the drug discounts available to covered entities.

Narrowing the criteria for organizations to be designated as covered entities, requiring specific application of 340B profits to charity care, and limiting the mark-up on the sale of 340B products to private payers (or eliminating the 340B discount for privately insured patients) are all approaches that can all reduce the distortions of the 340B program. None are likely to be politically popular, and it will be important to ensure that the elimination of 340B does not result in a financial windfall for pharmaceutical manufacturers. Unfortunately, changes in the organization of care from community to hospital-based treatment may persist even with the most aggressive reforms to the 340B program.

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